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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,657	02/19/1999	PETER RUHDAL JENSEN	55411.000002	1335

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,657

Applicant(s)

JENSEN ET AL.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-132)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 1-3-02 has been entered. In Paper No. 22, claims were amended (claims 1, 16, 18, 21) and new claims added (claims 23-28). Claims 1-28 are pending.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no computer readable format (CRF) was filed, no paper sequence was filed and no attorney statement was filed. These sequences include **Claims 26 and 28 comprise a sequence that requires a SEQ ID NO under the sequence rules. If the sequence is already present in the current sequence listing, it would be remedial to simply amend the claim language by inserting the appropriate sequence identifier number following the sequence.** If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R.

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1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 23-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a set of promoters suitable for optimizing expression of a gene in a selected organism or group of organisms, methods of construction of the set of promoter sequences and methods of using subsets of promoter sequences obtained from the first set of promoter sequences.

Claims 1, 16 and 21 comprise the newly added phrase of "...by inserting each of the set of promoters into a vector comprising a promoterless B-galactosidase reporter gene system, transforming a host strain with the resulting vector and cultivating the transformed host strain with the resulting vector and cultivating the transformed host strain to express B-galactosidase from the reporter gene and identifying that promoter set showing the weakest B-galactosidase activity...by the same procedure with the exception that the promoter of the promoter set showing the strongest activity in said report gene is identified..." There does not appear to be literal support in the specification, however, for performing construction of such a promoter

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library wherein a range of promoter strengths is identified by the specified B-galactosidase reporter-gene system. The pages cited in applicants' response (pages 1,2 and 7) do not appear to provide such support. This is particularly evident for claim 1 where the set of promoters must exhibit a step-wise increase in product from weakest to strongest promoter of 50-100% increase in activity per step. Therefore, the addition of the cited phrase to the claims constitutes impermissible NEW MATTER.

Claims 1-15 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a set of promoters suitable for optimizing expression of a gene in a selected organism or group of organisms and methods of using subsets of promoter sequences obtained from the first set of promoter sequences. Claim 1 comprises a new limitation wherein the at least two consensus sequences of the promoter library are defined in terms of a pair of Markush groups (one each for prokaryotic and eukaryotic cells). There does not appear to be literal support in the specification for these two Markush groups. Therefore, these newly added Markush groups are considered to be impermissible NEW MATTER.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a set of promoters suitable for optimizing expression of a gene in a selected organism or group of organisms. New claim 23 comprises a Markush group consisting of several activator-binding sites upstream of the TATAAT sequence. There does not appear to be literal support in the specification for this Markush group. Therefore, this limitation is considered to be impermissible NEW MATTER.

Claims 1-21, 23-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a set of promoters suitable for optimizing expression of a gene in a selected organism or group of organisms and methods of using subsets of promoter sequences obtained from the first set of promoter sequences.

The claims drawn towards a set of promoter sequences (claims 1-15 and 23-28) or to methods of using the set of promoter sequences (claims 18-20) still encompass an enormous number of potential promoter sequences. The set of promoter sequences encompassed by these claims promote expression of B-galactosidase in a prokaryotic or eukaryotic cell at levels that range from the weakest detectable to strongest detectable by a B-galactosidase assay. The set of promoters must also satisfy the functional limitation of exhibiting in a step-wise fashion 50-100% changes in promoter activity from "adjacent" members in the set of promoters. While the

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claims have been limited to specify conserved regions within the promoter set, there remains no structural/functional basis for one of skill in the art to envision those promoter sets that 1) retain the conserved sequences and 2) satisfy the functional limitations of the claim with regard to step-wise increments in promoter activity amongst the members of the promoter set for literally any cell type. Therefore, one of skill in the art would not have been able to envision a representative number of specific promoter sets to describe the broad genus of promoter sets encompassed by the rejected claims. One of skill in the art would thus have reasonably concluded applicants were not in possession of the claimed invention for claims 1-15, 23-28.

Claims 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Both of the claims comprise the limitation "...the sense strand of the double stranded DNA sequence comprises the sequence CTCTTAAGTACTGCGA as further consensus sequence..." However, there does not appear to be literal support in the specification as filed for this further consensus sequence. Therefore, the addition of this limitation is considered to be impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-21 and 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 16 and 21 are vague and indefinite in that the metes and bounds of the phrase "...to the strongest activity that is detectable by the same procedure with the exception that the promoter of the promoter set showing the strongest activity in said reporter gene system is identified..." are unclear. What is intended by the term "identified"? Does this mean that the promoter is sequenced? Or does this phrase simply specify that the procedure be repeated to identify a range of activities from weakest to strongest? If the latter, it would be remedial to simplify the claim language to more clearly indicate that promoters expressing B-galactosidase activity over a range from weakest to strongest activity are identified.

Claims 1, 16 and 21 are also vague and indefinite in that the metes and bounds of the phrase "identifying the promoter set" are unclear. It is unclear whether the step of identifying a "promoter set" of weakest or strongest activity specifies the identification of a subset of promoters that are weak or strong or whether the phrase is meant to specify identification of individual promoters over the entire range. It would be remedial to amend the specification to more clearly indicate whether the term "promoter set" as it is used in these claims specifies a single promoter or a subset of promoters.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...the set of promoter sequences covering the range of promoter activities for said gene, in steps, each step changing the activity by 50-100%..." are unclear. There is no clear and positive prior antecedent

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basis for the term “said gene” in this phrase. Does the term refer to the B-galactosidase gene or to the desired gene?

Claim 16 is vague and indefinite in that the metes and bounds of the phrase “...at least two consensus sequences, said at least two consensus sequences corresponding to conserved sequences identified in said organism or group of organisms...” are unclear. What exactly constitutes a “conserved sequence”? How much variation is allowable for two sequences to still be considered “conserved”? It would be remedial to amend the claim language to include language similar to that used in amended claim 1, wherein the “consensus” sequences are explicitly defined.

Claim 16 is also vague and indefinite in that the metes and bounds of the phrase “...comprising at least half of each of the consensus sequences...” are unclear. Does the phrase specify that the same nucleotides are absolutely conserved amongst all of the promoters in the set, or does the phrase specify that within the population of promoters each promoter comprises half of the consensus sequence.

Claim 16, part (iii), is vague and indefinite in that it is unclear whether the step of converting the single stranded DNA sequences of step (ii) into a double stranded DNA necessarily results in obtaining the promoter set having a range of promoter activity with regard to B-galactosidase from weakest to strongest, or whether an additional step of inserting each of the promoters within the set into a vector and performing B-galactosidase assays to obtain the desired promoters is required. If the latter were the case, then it would be remedial to separate the two steps so that it is clear that there are actually two steps (e.g. part (iv)).

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Claim 28 is vague and indefinite in that it purports to be dependent upon itself. It would be remedial to amend the claim language to make claim 28 dependent upon another claim.

Conclusion

Claim 22 is allowed. Each of the promoter sequences recited in claim 22 appears to be free of the art. Claims 1-21 and 23-28 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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February 25, 2002

DAVID GUZO
PRIMARY EXAMINER

David Guzo